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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,522	05/08/2006	Steven M. Leventer	18184001801US	5139

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EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,522	LEVENTER ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

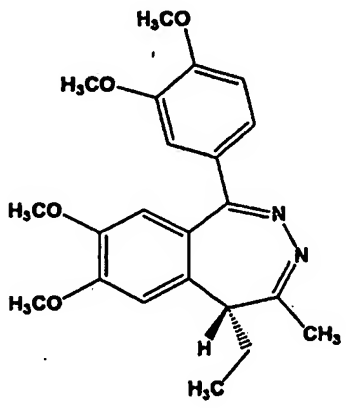
Claims 1-21 are pending currently. Claims 1-9 and 16-21 are pending and they are the subject of this Office Action. Claims 10-15 are withdrawn from consideration, are withdrawn from consideration because they are not directed to the elected species.

Priority Assigned to Claims

Applicants claim priority for this Application dating back to 03 December 2003, the date of filing for U.S. Patent Application No. 10/727,940, for which the instant application is a continuation in part. Upon review of the disclosures contained therein, the Office concludes that the assignment of 03 December 2003 to the instant application is proper. For this reason, prior art for 35 U.S.C. §102(b) purposes herein are defined as being on or before 03 December 2003.

Election of Species

During a telephone conversation with Daniel Monaco on 23 October 2007 a provisional election was made, with traverse, to prosecute the disclosed invention, a method of treating an individual afflicted with an inflammatory disorder of epithelial tissue comprising the administration of the following compound:



(R)-tofisopam

An affirmation of this election must be made by the Applicants, when replying to this Office Action. Claims 10-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The election was made with traverse, because Applicants wish the election to include the stereoisomers of the above compound. The Examiner takes the position the stereoisometric forms of the above compound are patentably distinct and therefore, properly excluded from consideration.

It is well-known in the art, generally, that active biological processes, including, for example, receptor interaction, enzyme action, and binding specificity, for example, either alone or in combination may affect the therapeutic actions of a stereoisomer *in vivo*. *See* U.S. Patent No. 6,080,736 [hereinafter referred to as "Landry et al"] at Col. 2, lines 47-55.[1] Specifically with regard to (R)-tofisopam, pharmacological tests in mice [] show different biological activity for the stereoisomers, including the observation that the activity of racemic tofisopam does not correspond with the sum of the activities of its enantiomers (*Id.* at Col. 9, lines 2-6). These two points, taken together, are suggestive that the stereoisometric forms of (R)-tofisopam, are patentably distinct from the compound itself.

Should applicant traverse on the ground that the inventions or species are not patentably distinct as indicated, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the

[1] Cited on Form PTO-1449 provided by the Applicants.

prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 16-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,864,251 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '251 patent claims a method of treating an individual afflicted with an inflammatory disorder mediated by LTB_4 comprising the administration of the compound of the present invention while the present application is drawn to a method of treating an individual afflicted with an inflammatory disorder generally. The methods articulated in claims 1-12 of the '251 patent overlap in scope with the methods articulated in claims 1-9 and 16-21 of the instant invention.

For example, the instant application claims a method of treating an inflammatory condition of epithelial tissue that is a gastrointestinal disorder while the '940 application contemplates only the treatment of an inflammatory condition that is mediated by LTB_4. Both are, however, directed to treating inflammatory conditions and it is know in the art that LTB4 is chemotactic for leukocytes and plays in important role in the development of gastrointestinal ulcers by contributing to the inflammatory process. *See* Fiorucci, Stefano, "Dual Inhibitors of Cyclooxygenase and 5-lipoxygenase. A New Avenue in Anti-Inflammatory Therapy?" *Biochemical Pharmacology*, Vol. 62, pages 1433-1438 (2001)(Abstract).

Claims 1-9 and 16-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 13-14, and 29-31 of U.S. Patent Application No. 10/727,940. Although the conflicting claims are not identical, they

are not patentably distinct from each other because, for example, the instant application claims a method of treating an inflammatory condition of epithelial tissue that is a gastrointestinal disorder while the '940 application contemplates only the treatment of an inflammatory condition that is mediated by LTB_4. Both are, however, directed to treating inflammatory conditions and it is know in the art that LTB4 is chemotactic for leukocytes and plays in important role in the development of gastrointestinal ulcers by contributing to the inflammatory process. *See* Fiorucci, Stefano, "Dual Inhibitors of Cyclooxygenase and 5-lipoxygenase. A New Avenue in Anti-Inflammatory Therapy?" *Biochemical Pharmacology*, Vol. 62, pages 1433-1438 (2001)(Abstract).

In view of the foregoing, the present application is obviously a non-patentably distinct variation of the '940 Application.

This is a provisional rejection, because the claims have not, in fact, been patented.

In looking in continuity data, it is noted that applicant has numerous issued patents and pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, issued patents with the same or similar subject matter include but are not limited to 6,638,928, 6,683,072 and 7,022,700. Pending patent applications with the same or similar subject matter include, but are not limited to 10/846,822; 10/728,286; 10/781,422; 10/827,839; 11/388,399; 11/472,172; and 10/369823.

Claim Rejections - 35 U.S.C. §112.2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16-21 are rejected under 35 U.S.C. §112, second paragraph for indefiniteness for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention.

Claim 16 recites the terminology "substantially free of the corresponding (S)-enantiomers." The term "substantially" is a relative term which renders the language and therefore the subject claims, indefinite. The term "substantially" is not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree of the same. Thus, one or ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito, Chihiro, et al., "Pharmacological Studies of Tofiospam," *Res. Lab Pharmacol.*, Mochida Pharm. Co., Ltd., Tokyo, Japan (1981).

Ito, et al teach the pharmacological effects of tofiospam, both in vivo and in vitro, to include elevation in pain thresholds when administered orally. As discussed, supra, the instant invention as disclosed does not define the requisite degree of "substantially free of the corresponding (S)-enantiomers." In assigning therefore, the broadest reasonable interpretation, the claims are construed as encompassing tofiospam, which includes a 50:50 racemic mixture of (R) and (S) enantiomers. Therefore Ito, et al clearly anticipates the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

25 October 2007

Alicia Hughes

10/28/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER